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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/546,139	07/19/2006	Michel Chateau	34076/US/2	1181
25763 7590 08/03/2007 DORSEY & WHITNEY LLP INTELLECTUAL PROPERTY DEPARTMENT SUITE 1500 50 SOUTH SIXTH STREET MINNEAPOLIS, MN 55402-1498			EXAMINER LONG, SCOTT	
			ART UNIT 1633	PAPER NUMBER
			MAIL DATE 08/03/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/546,139	Applicant(s) CHATEAU ET AL.	
	Examiner Scott D. Long	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 July 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-37 is/are pending in the application.  
     4a) Of the above claim(s) 1-12 and 15-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/17/2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The examiner acknowledges receipt of claim amendments, and Traversal Remarks on 7/18/2007.

#### ***Election/Restrictions***

Examiner acknowledges the election, with traverse, of Group II directed to a method for the preparation of an evolved protein, in the reply filed on 19 April 2006.

The applicant traverses the restriction requirement because "claims 13 and 14 depend directly or indirectly from claims 11 and 1. Therefore to give meaning and substance to the claims 13 and 14, the subject matter of claims 11 and 1 should be considered concurrently with claims 13 and 14" (Remarks, page 9, filed 7/18/2007). Claim 1 is directed to a method for the preparation of evolved microorganisms. Claim 11 is directed to an evolved microorganism.

According to the Restriction Action (filed 6/20/2007) The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The inventions are drawn to multiple methods and a product, therefore as per 37 CFR § 1.475(a)-(d), applications containing claims drawn to more than one categories of invention (as defined by section (b)) are not considered to have unity of invention (see particularly section (c)). See the following:

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37 CFR § 1.475 Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage.

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

**(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.**

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

Therefore there is no special technical feature, as required for co-examination and restriction is required because there is no unity of invention or inventive step. A single group must be elected.

In addition, if a US restriction practice were applied, the inventions of groups including claims 1, 11, and 13-14 would be properly restrictable as follows:

Inventions of claim 1 and claim 11 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method of claim 1 can be used to make a large variety of microorganisms having completely different metabolic pathways, based on random mutations.

Inventions of claim 11 and claims 13-14 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case an evolved microorganism could be use to produce a byproduct, such as ethanol, from a genetically modified microorganism, rather than as a vehicle for a recombinant protein production.

Inventions of claim 1 and claims 13-14 are directed to unrelated processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed the method of producing a genetically modified microorganism (claim 1) has distinct steps from methods of purifying recombinant

proteins (claims 13-14), for example the protein purification step of claim 14.

Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, or divergent subject matter, or the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Therefore, under any means of restriction, the groups, traversed by the applicant would be considered properly restrictable. Therefore, the restriction is made final.

#### ***Claim Status***

Claims 1-37 are pending. However, claims 1-12 and 15-37 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Claims 13-14 are under current examination.

#### ***Sequence Compliance***

Sequence Listing and CRF have been received and are acknowledged by examiner. A statement that the Computer Readable Form (CRF) and the Sequence Listing are identical has been submitted and is acknowledged by examiner.

***Oath/Declaration***

The oath or declaration, having the signatures of all inventors, received on 15 November 2005 is in compliance with 37 CFR 1.63.

***Information Disclosure Statement***

The Information Disclosure Statements (IDS) filed on 17 August 2005 consisting of 1 sheets are in compliance with 37 CFR 1.97. Accordingly, examiner has considered the Information Disclosure Statements.

***Priority***

This application claims benefit as a 371 of PCT/FR04/00354 (filed 02/17/2004). The instant application has been granted the benefit date, 17 February 2004, from the application PCT/FR04/00354.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Schnappinger et al (Arch. Microbiol. 1996; 165: 359-369).

Claims 13 is directed to a method for the preparation of an evolved protein, wherein the evolved microorganism according claim 11 is cultivated in a culture medium appropriate for the production of the evolved protein. The specification defines an evolved protein as "a sequence of amino acids (protein sequence) that differs in at least on amino acid from the initial protein sequence after selection" (page 4, lines 5-8). According to the specification, selection is defined as "a culture method used to select microorganisms that have evolved in such a way that a modification does not affect growth anymore" (page 3, lines 22-24). The examiner is broadly interpreting the evolved microorganism according to claim 11 to be any microorganism having undergone a selection process and which comprising an amino acid change in a protein. Schnappinger et al. teach "Tet(M) ribosomal protection protein resembles elongation factors...it has amino acid sequence similarity to EF-F and EF-Tu" (page 362, first parag.). Schnappinger et al. et al teach Streptococcus spp. Bearing Tet(M) accumulates tetracycline to the level similar to that observed in sensitive cells.



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Schnappinger et al. further describes the culturing of microorganisms comprising Tet(M). (page 361, col.2, 2<sup>nd</sup> parag.). Schnappinger et al. teach "The ribosomal protection proteins encoded by the other classes have an amino acid sequence similarity of at least 40% to Tet(M)" (page 361, col.2, 1<sup>st</sup> parag.). Regardless of which gene evolved from which, Tet(M) is an evolved protein, in the sense of the instant specification. Schnappinger et al. clearly teach culturing microorganisms comprising the evolved protein Tet(M).

Claim 14 is directed to the method as claimed in Claim13, characterized in the produced evolved protein is purified. Schnappinger et al. teach "Tet(M) protein was subsequently purified" (page 361, last paragraph).

Accordingly, Schnappinger et al. anticipated the instant claims.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13 –14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-17 of copending Application No 10/781499. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets are drawn to purifying evolved proteins.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claims are allowed.

***Examiner Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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JLE